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| 10/591,095 | 09/20/2006 | Valerie Frankard | 14546-00001-US | 4358 |

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| EXAMINER | |
|---|---|
| COLLINS, CYNTHIA E | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/591,095 | FRANKARD, VALERIE | |
| | Examiner | Art Unit | |
| | Cynthia Collins | 1638 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *04 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-18 and 20-24* is/are pending in the application.

4a) Of the above claim(s) *10 and 11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,12-18 and 20-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *August 29, 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *121306,82906*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

***Election/Restrictions***

Applicant's election with traverse of **Group I**, claim(s) 1-9, 12, 16-18, 20-21 and 23-24, drawn to a method comprising introducing into a plant a nucleic acid encoding a D-type Cyclin Dependent Kinase (CDKD), and plants produced by said method, in the reply filed on June 4, 2008 is acknowledged.

The traversal is on the ground(s) that the general inventive concept of the present invention, a method for increasing plant yield by altering expression of a nucleic acid encoding a D-type CDK, is the technical feature linking the groups of invention, a method for increasing plant yield by altering expression of a nucleic acid encoding a D-type CDK being a special technical feature not taught in the prior art.

This is not found persuasive because increased plant yield is merely a consequence of the technical feature linking the groups of invention (a nucleic acid encoding a D-type CDK), which technical feature is not a special technical feature because it is taught in the prior art. This is also not found persuasive because, as set forth below, only claims 16-17 and 24 are limited by increased plant yield.

The traversal is also on the ground(s) that the Examiner has required restriction between product (Group II) and process claims (Groups I and III-VI), whereas under the applicable standard, claims directed to a product and a process of making and of using said product are an acceptable combination of categories under unity pursuant to 37 CFR § 1.475(b)(3).

This is not found persuasive because Group II is not linked by a special technical feature to groups I and III-VI.

The traversal is additionally on the ground(s) that there is no undue burden on the Examiner to search and examine all groups together, since all the claims share the same technical feature (a nucleic acid encoding a D-type CDK).

This is not found persuasive because the searches of all groups of invention are not coextensive. The searches of groups I-VI are not limited to a search of a nucleic acid encoding a D-type CDK. A search of Group I requires a search for methods of introducing CDKD coding nucleic acids into plants, which is not required for a search of groups II-VI. A search of Group II requires a search for constructs, which is not required for a search of groups I and III-VI. A search of Group III requires a search for site-directed mutagenesis methods of genetic modification, which is not required for a search of groups I-II and IV-VI. A search of Group IV requires a search for homologous recombination methods of genetic modification, which is not required for a search of groups I-III and V-VI. A search of Group V requires a search for tilling methods of genetic modification, which is not required for a search of groups I-IV and VI. A search of Group VI requires a search for T-DNA inactivation methods of genetic modification, which is not required for a search of groups I-V. Because the searches of groups I-VI are both not coextensive and divergent in subject matter, a search of all 6 groups would be unduly burdensome.

The traversal is additionally on the ground(s) that at least Groups I and II should be examined together, since both Groups I and II relate to using a nucleic acid encoding a CDKD.

This is found persuasive in view of the search results, and Groups I and II are rejoined and examined together herein.

Accordingly, 1-9, 12-18 and 20-24 are examined herein.

Claims 10-11 are withdrawn from consideration as being directed to nonelected inventions.

The requirement is still deemed proper and is therefore made FINAL.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 5 is drawn to a method for increasing plant yield relative to corresponding wild type plants, comprising introducing into a plant and overexpressing a nucleic acid encoding a plant D-type Cyclin Dependent Kinase (CDKD) driven by a constitutive promoter wherein the nucleic acid encoding a CDKD is represented by SEQ ID NO: 1 or

is a functional variant thereof and wherein the CDKD polypeptide is represented by SEQ ID NO: 2 or is a functional variant thereof, which functional variant is selected from the group consisting of: (i) Portions of a nucleic acid represented by the sequence of SEQ ID NO: 1; (ii) Sequences capable of hybridising to a nucleic acid represented by the sequence of SEQ IDNO: 1; (iii) Alternative splice variants of a nucleic acid represented by the sequence of SEQ ID NO: 1; (iv) Allelic variants of a nucleic acid represented by the sequence of SEQ ID NO: 1; and (v) Homologues, derivatives and active fragments of an amino acid sequence represented by the sequence of SEQ ID NO: 2.

With respect to functional variants of SEQ ID NOS: 1 and 2 that are (i) Portions of a nucleic acid represented by the sequence of SEQ ID NO: 1; (ii) Sequences capable of hybridising to a nucleic acid represented by the sequence of SEQ ID NO: 1; (iii) Alternative splice variants of a nucleic acid represented by the sequence of SEQ ID NO: 1; (iv) Allelic variants of a nucleic acid represented by the sequence of SEQ ID NO: 1; and (v) Homologues, derivatives and active fragments of an amino acid sequence represented by the sequence of SEQ ID NO: 2, neither the specification nor the prior art of record describe the structure of any functional variant of SEQ ID NOS: 1 and 2 that have the recited characteristics.

The Federal Circuit has clarified the application of the written description requirement to nucleic acids. The court stated that "A description of a genus of cDNAs may be achieved by means of recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1569; 43

USPQ2d 1398, 1406 (Fed. Cir. 1997). The court has also affirmed the PTO's applicable standard for determining compliance with the written description requirement, quoting from the PTO's Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, P1, "Written Description" Requirement, 66 Fed. Reg. 1099, 1106, where it is set forth that the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ... i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." See *Enzo Biochem Inc. v. Gen-Probe Inc.*, 63 USPQ2d 1609, 1613 (CAFC 2002).

In the instant case Applicant has not described a representative number of species falling within the scope of the claimed genus, nor the structural features unique to the genus. In the instant case Applicant also has not disclosed sufficiently detailed, relevant identifying characteristics of variants of SEQ ID NOS: 1 and 2 that are (i) to (v) that are coupled with a known or disclosed correlation with the function of SEQ ID NOS: 1 and 2.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 4 is indefinite in requiring the introduction into a plant of "a nucleic acid encoding a CDKD or functional variant

thereof". It is unclear whether the nucleic acid recited in claim 4 is the same as, or in addition to, the nucleic acid recited in claim 1 from which claim 4 depends, since there is no antecedent basis for "or a functional variant thereof" in claim 1. Likewise, Claim 5 is indefinite in requiring the introduction into a plant of a nucleic acid that is or encodes "a functional variant". It is unclear whether the nucleic acid recited in claim 5 is the same as, or in addition to, the nucleic acid recited in claim 1 from which claim 5 depends, since there is no antecedent basis for "a functional variant" in claim 1.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 is indefinite in the recitation of "capable of". It is unclear whether actual hybridization to a nucleic acid represented by the sequence of SEQ ID NO:1 is required by the claim.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 21 is indefinite in the recitation of "Homologues, derivatives and active fragments of an amino acid represented by the sequence of SEQ ID NO:2", as SEQ ID NO:2 is an amino acid sequence, not an amino acid.

Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 21 is indefinite in the recitation of "wherein said CDKD is an amino acid as represented by SEQ ID NO:2 or a functional variant thereof", as SEQ ID NO:2 is an amino acid sequence, not an amino acid.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Fabian-Marwedel T. et al. (The rice cyclin-dependent kinase-activating kinase R2 regulates S phase progression. Plant Cell. 2002 Jan;14(1):197-210).

The claims are drawn to a construct comprising: a CDKD-encoding nucleic acid or a functional variant thereof; (ii) one or more control sequence capable of driving expression of the nucleic acid sequence of including a constitutive promoter (i); and optionally (iii) a transcription termination sequence.

Fabian-Marwedel T. et al. a construct comprising (i) a rice plant CDK-activating kinase R2 encoding nucleic acid; (ii) a maize ubiquitin promoter; and (iii) a nopaline synthase terminator sequence (page 207 column 2). The rice plant CDK-activating kinase R2 encoding nucleic acid is a CDKD-encoding nucleic acid (Joubes J. et al. CDK-related protein kinases in plants. Plant Mol Biol. 2000 Aug;43(5-6):607-20. Review. See page 612 Table 1). Fabian-Marwedel T. et al. describes expression from the maize ubiquitin promoter as constitutive (page 201 column 1).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9, 12, 15, 18, 20-21 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fabian-Marwedel T. et al. (The rice cyclin-dependent kinase-activating kinase R2 regulates S phase progression. Plant Cell. 2002 Jan;14(1):197-210) in view of Komari T. et al. (Advances in cereal gene transfer. Curr Opin Plant Biol. 1998 Apr;1(2):161-5. Review).

The claims are drawn to a plant transformed with a construct comprising: a CDKD-encoding nucleic acid or a functional variant thereof; (ii) one or more control sequence capable of driving expression of the nucleic acid sequence of including a constitutive promoter (i); and optionally (iii) a transcription termination sequence.

The claims are also drawn to a method for increasing plant yield relative to corresponding wild type plants, comprising introducing into a plant and overexpressing a nucleic acid encoding a plant D-type Cyclin Dependent Kinase (CDKD) driven by a constitutive promoter, including a method wherein the nucleic acid encoding a CDKD is represented by SEQ ID NO: 1 or is a functional variant thereof and wherein the CDKD polypeptide is represented by SEQ ID NO: 2 or is a functional variant thereof, which functional variant is selected from the group consisting of: (i) Portions of a nucleic acid represented by the sequence of SEQ ID NO: 1; (ii) Sequences capable of hybridising to a nucleic acid represented by the sequence of SEQ IDNO: 1; (iii) Alternative splice variants of a nucleic acid represented by the sequence of SEQ ID NO: 1; (iv) Allelic variants of a nucleic acid represented by the sequence of SEQ ID NO: 1; and (v) Homologues, derivatives and active fragments of an amino acid sequence represented by

the sequence of SEQ ID NO: 2, a plant obtainable by said method, and harvestable parts thereof.

The teachings of Fabian-Marwedel T. et al. are set forth above. Fabian-Marwedel T. et al. also teach rice plant cells transformed with a construct comprising (i) a rice plant CDK-activating kinase R2 encoding nucleic acid; (ii) a maize ubiquitin promoter; and (iii) a nopaline synthase terminator sequence (page 201 Figure 3; page 202 Figure 4). Additionally, the rice plant CDK-activating kinase R2 encoding nucleic acid taught by Fabian-Marwedel T. et al. is a CDKD-encoding nucleic acid (see above). Further, the rice plant CDK-activating kinase R2 encoding nucleic acid taught by Fabian-Marwedel T. et al. is a functional variant of SEQ ID NO:1 and encodes a functional variant of SEQ ID NO:2 because it encodes a CDKD. Also, the rice plant CDK-activating kinase R2 encoding nucleic acid taught by Fabian-Marwedel T. et al. is capable of hybridising to a nucleic acid represented by the sequence of SEQ IDNO: 1 because it has 71.3% best local similarity to SEQ ID NO:1 (see attached sequence alignment between SEQ ID NO:1 and Hata S. GenBank Accession No. X58194. *O. sativa* mRNA for cdc2+/CDC28-related protein kinase. April 18, 2005). Fabian-Marwedel T. et al. also teach that increasing R2 abundance through a transgenic approach accelerates S-phase progression and overall growth rate in suspension cells (abstract; page 202 Figure 4; page 203 Figures 5 and 6).

Fabian-Marwedel T. et al. do not teach a transformation method wherein transgenic rice plants per se are produced.

Komari T. et al. teach that transformation methods wherein transgenic cereal plants per se are produced was known and practiced in the art prior to Applicant's filing date, and that rice was considered to be the cereal plant in which transformation-related

technology was most advanced, being the model monocotyledon for basic and applied transformation studies.

It is also noted that while neither Fabian-Marwedel T. et al. nor Komari T. et al. teach transformation "for increasing plant yield relative to corresponding wild type plants" or "for the production of a transgenic plant having increased yield", Fabian-Marwedel T. et al. and Komari T et al. need not teach these limitations in order to render the rejected claims obvious, since these limitations, recited in the preambles of claims 1 and 8, are intended uses and are thus not limiting.

Given the teachings of Fabian-Marwedel T. et al. that rice plant cells transformed with a construct comprising a rice plant CDK-activating kinase R2 encoding nucleic acid and a maize ubiquitin promoter have an accelerated S-phase progression and overall growth rate, and given the teachings of Komari T. et al. that the production of transgenic rice plants was known and practiced in the art prior to Applicant's filing date, it would have been *prima facie* obvious to one skilled in the art at the time the invention was made to produce transgenic rice plants from rice plant cells transformed with a construct comprising a rice plant CDK-activating kinase R2 encoding nucleic acid and a maize ubiquitin promoter. One skilled in the art would have been motivated to do so in order to determine the effect of overexpressing a rice plant CDK-activating kinase R2 encoding nucleic acid at the whole plant level. One skilled in the art would have had a reasonable expectation of success given the success of Fabian-Marwedel T. et al. in overexpressing a rice plant CDK-activating kinase R2 encoding nucleic acid in rice plant cells and given the overall success of others in producing transgenic rice plants as taught by Komari T. et al. Accordingly, one skilled in the art would have been motivated to generate the claimed

invention with a reasonable expectation of success. Thus, the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time the invention was made.

Claims 16-17 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fabian-Marwedel T. et al. (The rice cyclin-dependent kinase-activating kinase R2 regulates S phase progression. Plant Cell. 2002 Jan;14(1):197-210) in view of Komari T et al. (Advances in cereal gene transfer. Curr Opin Plant Biol. 1998 Apr;1(2):161-5. Review) and Cornejo M. et al. (Activity of a maize ubiquitin promoter in transgenic rice. Plant Mol Biol. 1993 Nov;23(3):567-81).

The claims are drawn to a transgenic monocotyledonous cereal plant having increased yield, wherein said plant comprises an isolated nucleic acid encoding a CDKD or a functional variant thereof.

The teachings of Fabian-Marwedel T. et al. and are set forth above. Fabian-Marwedel T. et al. also teach that the control of R2 kinase activity is linked to cell proliferation in planta, as the CTD kinase activity of R2 is increased in cells induced to divide rapidly (page 205 column 1 first paragraph). Fabian-Marwedel T. et al. additionally teach that R2 overexpression increases the growth of rice cells in suspension, resulting in increased fresh weight (i.e. yield) in transgenic cells as compared to nontransformed wild type cells (page 203 Figure 6).

Fabian-Marwedel T. et al. do not teach a transformation method wherein transgenic rice plants per se are produced.

The teachings of Komari T et al. and are set forth above.

Komari T et al. do not teach a transgenic monocotyledonous cereal plant having increased yield.

Cornejo M. et al. teach that the maize ubiquitin promoter is most active in rapidly dividing rice cells and is expressed in many, but not all, rice plant tissues, including the meristematic (dividing) cells of young roots (abstract; page 577 column 2; page 576 Figure 6).

Given the teachings of Fabian-Marwedel T. et al. that rice plant cells transformed with a construct comprising a rice plant CDK-activating kinase R2 encoding nucleic acid and a maize ubiquitin promoter have an accelerated S-phase progression and overall growth rate, that the control of R2 kinase activity is linked to cell proliferation in planta, as the CTD kinase activity of R2 is increased in cells induced to divide rapidly, and that R2 overexpression increases the growth of rice cells in suspension, resulting in increased fresh weight (i.e. yield) in transgenic cells as compared to nontransformed wild type cells, and given the teachings of Komari T et al. that the production of transgenic rice plants was known and practiced in the art prior to Applicant's filing date, it would have been *prima facie* obvious to one skilled in the art at the time the invention was made to produce transgenic rice plants from rice plant cells transformed with a construct comprising a rice plant CDK-activating kinase R2 encoding nucleic acid and a maize ubiquitin promoter.

One skilled in the art would have been motivated to do so in order to produce transgenic rice plants (a monocotyledonous cereal plant) having increased yield. One skilled in the art would have had a reasonable expectation of success, given the success of Fabian-Marwedel T. et al. in increasing growth and fresh weight of rice plant cells by

overexpressing a rice plant CDK-activating kinase R2 encoding nucleic acid from a maize ubiquitin promoter in rice plant cells, given the teachings of Fabian-Marwedel T. et al. that R2 kinase activity is also linked to cell proliferation in planta, given the overall success of others in producing transgenic rice plants as taught by Komari T et al., and given the teachings of Cornejo M. et al. that the maize ubiquitin promoter is active in dividing (proliferating) rice cells in planta.

Accordingly, one skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success. Thus, the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time the invention was made.

***Remarks***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cynthia Collins/
Primary Examiner, Art Unit 1638

CC